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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,945	09/24/2002	Christopher John Andrews	PPD 50449/ UST	4663

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EXAMINER

PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,945

Applicant(s)

ANDREWS ET AL.

Examiner

Rebecca E. Prouty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 22-24 and 26-41 is/are pending in the application.
- 4a) Of the above claim(s) 3-20, 22-24 and 27-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claims 21 and 25 have been canceled. Claims 1-20, 22-24, and 26-41 are at issue and are present for examination.

Applicant's election without traverse of Group I, Claims 1, 2, and 26 in the response filed 1/13/05 is acknowledged.

Claims 3-20, 22-24, and 27-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse the response filed 1/03/05.

Applicants amendment to the specification of 9/24/02 is objected to as it incorrectly identifies the relationship of the instant specification to PCT/GB00/03573. The instant application is a 371 national stage filing of the international applicant **not** a continuation of the international application. Correction is required.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is indefinite in the recitation of "having a Smith-Waterman Score of at least 766 using a FASTA3 algorithm" as the specification does not provide any description of what level of identity to SEQ ID NO:10 a sequence having a Smith-

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Waterman Score of at least 766 using a FASTA3 algorithm corresponds to and a review of the references cited by applicant for this program do not appear to provide this information. As such the scope of the claims is unclear. As the sequence identity software available in the Office does not use this algorithm, for purposes of examination the examiner has assumed that the Smith-Waterman score obtained using the software available in the Office would be similar to that using the FASTA3 algorithm. If this is incorrect applicants should provide an indication of what level of identity this score corresponds to.

Claims 1, 2, and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the glutathionine-S-transferase (GST) of SEQ ID NO:10, does not reasonably provide enablement for any GST at least having at least 80% identity to SEQ ID NO:10 or having a Smith-Waterman Score of at least 766 using a FASTA3 algorithm. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1, 2, and 26 are so broad as to encompass any GST having at least 80% identity to SEQ ID NO:10 or having a Smith-

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Waterman Score of at least 766 using a FASTA3 algorithm. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of GST enzymes broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the GST of SEQ ID NO:10.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish

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with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass having any GST having at least 80% identity to SEQ ID NO:10 or having a Smith-Waterman Score of at least 766 using a FASTA3 algorithm because the specification does not establish: (A) regions of the protein structure which may be modified without effecting GST activity; (B) the general tolerance of GSTs to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any GST having at least having 80% identity to SEQ ID NO:10 or having a Smith-Waterman Score of at least 766 using a FASTA3 algorithm. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of GSTs having the desired

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biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 26 is rejected under 35 U.S.C. 102(e) as being anticipated by McGonigle et al. (US Patent 6,063,570, Reference A of Applicants 1449).

McGonigle et al. teach a soybean GST sequence (SEQ ID NO:8 in McGonigle et al.) having a Smith-Waterman Score of 1000.5 using the Office's software package (see rejection under 112, 2nd above for interpretation of scope of the claim) and thus anticipates the instant claim.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior

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art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGonigle et al. (US Patent 6,063,570, Reference A of Applicants 1449) in view of Gulick et al. and Skipsey et al. (Reference W of Applicants 1449)

McGonigle et al. teach a soybean GST sequence having 84% identity to SEQ ID NO:10 and teach the usefulness of this sequence for the detoxification of herbicides and thus the production of transgenic plants having increased resistance to herbicides.

Gulick et al. teach methods of evolving a GST encoding sequence to create an enzyme which more efficiently detoxifies a particular compound of interest which comprises mutating selected regions of the GST substrate binding site followed by selection for mutants having increased resistance to the

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compound of interest. Gulick et al. obtained a 6-fold increase in the resistance to a particular drug of interest.

Skipsey et al. teach that a number of herbicides which are used to control weeds selectively in soybeans are detoxified by conjugation with homoglutathione (see page 370). Skipsey teach that these herbicides include acifluorfen and fomesafen among others (see Table 1).

Therefore, it would have been obvious to one of ordinary skill in the art to evolve the soybean GST taught by McGonigle et al. using the methods taught by Gulick et al. to select for GSTs with increased activity against the commonly used soybean herbicides as one of skill in the art would reasonable expect these mutant enzymes to be useful for production of transgenic soybeans having increased resistance to the herbicides used to control weeds in soybean fields. One of ordinary skill in the art would have a reasonable expectation of obtaining a mutant of the enzyme of McGonigle et al. with increased resistance to acifluorfen or fomesafen in view of the success of Gulick et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (571) 272-0937. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura

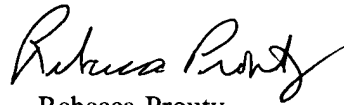
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Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Rebecca Prouty", with a stylized, cursive script.

Rebecca Prouty
Primary Examiner
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